

DRAFT CLAIM SET  
10/816,567 (00032.04CON)

1. (currently amended) A composition condensation aerosol for delivery of benztropine consisting of a condensation aerosol a drug selected from the group consisting of benztropine, pergolide, amantadine, deprenyl and ropinerole.
  - a) wherein the condensation aerosol is formed by volatilizing heating a thin layer of benztropine containing the drug, on a solid support, having the surface texture of a metal foil, to a temperature sufficient to produce a heated vapor of benztropine the drug and condensing the heated vapor of benztropine to form a condensation aerosol particles;
  - b) wherein said condensation aerosol particles are characterized by less than 5% benztropine 10% drug degradation products by weight, and
  - c) the condensation aerosol has an MMAD of less than 3.5 microns.
2. (currently amended) The composition condensation aerosol according to Claim 1, wherein the condensation aerosol particles are is formed at a rate of at least greater than 10<sup>9</sup> particles per second.
3. (currently amended) The composition condensation aerosol according to Claim 2, wherein the condensation aerosol particles are is formed at a rate of at least greater than 10<sup>10</sup> particles per second.
4. (currently amended) The composition condensation aerosol according to Claim 1 37, wherein said the condensation aerosol particles are is characterized by less than 2.5% benztropine drug degradation products by weight.

5-19. (cancelled)

20. (currently amended) A method of producing benztropine a drug selected from the group consisting of benztropine, pergolide, amantadine, deprenyl and ropinerole in an aerosol form comprising:
  - a. heating a thin layer of benztropine containing the drug, on a solid support, having the surface texture of a metal foil, to a temperature sufficient to volatilize

DRAFT CLAIM SET  
10/816,567 (00032.04CON)

~~the benztropine to form a heated vapor of the benztropine drug, and~~

b. ~~during said heating, passing air providing an air flow through the heated vapor to produce a condensation aerosol particles of the benztropine comprising characterized by less than 5% benztropine 10% drug degradation products by weight, and an aerosol having an MMAD of less than 3.5 microns.~~

21. (original) The method according to Claim 20, wherein the condensation aerosol particles are is formed at a rate of greater than  $10^9$  particles per second.

22. (original) The method according to Claim 21, wherein the condensation aerosol particles are is formed at a rate of greater than  $10^{10}$  particles per second.

23-34. (cancelled)

35. (new) The condensation aerosol according to Claim 1, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 5 microns.

36. (new) The condensation aerosol according to Claim 1, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.

37. (new) The condensation aerosol according to Claim 36, wherein the condensation aerosol is characterized by an MMAD of 0.2 and 3 microns.

38. (new) The condensation aerosol according to Claim 1, wherein the condensation aerosol is characterized by less than 5% drug degradation products by weight.

39. (new) The condensation aerosol according to Claim 1, wherein the thin layer contains at least 80% drug by weight.

40. (new) The condensation aerosol according to Claim 39, wherein the thin

DRAFT CLAIM SET  
10/816,567 (00032.04CON)

layer contains at least 95% drug by weight.

41. (new) The condensation aerosol according to Claim 1, wherein the condensation aerosol comprises at least 80% drug by weight.

42. (new) The condensation aerosol according to Claim 41, wherein the condensation aerosol comprises at least 95% drug by weight.

43. (new) The condensation aerosol according to Claim 1, wherein the solid support has the surface texture of a metal foil.

44. (new) The condensation aerosol according to Claim 1, wherein the solid support is a metal foil.

45. (new) The condensation aerosol according to Claim 1, wherein the drug is benzotropine.

46. (new) The condensation aerosol according to Claim 1, wherein the drug is pergolide.

47. (new) The condensation aerosol according to Claim 1, wherein the drug is amantadine.

48. (new) The condensation aerosol according to Claim 1, wherein the drug is deprenyl.

49. (new) The condensation aerosol according to Claim 1, wherein the drug is ropinerole.

50. (new) The method according to Claim 20, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 5 microns.

DRAFT CLAIM SET  
10/816,567 (00032.04CON)

51. (new) The method according to Claim 20, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.

52. (new) The method according to Claim 51, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 3 microns.

53. (new) The method according to Claim 20, wherein the condensation aerosol is characterized by less than 5% drug degradation products by weight.

54. (new) The method according to Claim 53, wherein the condensation aerosol is characterized by less than 2.5% drug degradation products by weight.

55. (new) The method according to Claim 20, wherein the thin layer contains at least 80% drug by weight.

56. (new) The method according to Claim 55, wherein the thin layer contains at least 95% drug by weight.

57. (new) The method according to Claim 20, wherein the condensation aerosol comprises at least 80% drug by weight.

58. (new) The method according to Claim 57, wherein the condensation aerosol comprises at least 95% drug by weight.

59. (new) The method according to Claim 20, wherein the solid support has the surface texture of a metal foil.

60. (new) The method according to Claim 20, wherein the solid support is a metal foil.

61. (new) The method according to Claim 20, wherein the drug is

DRAFT CLAIM SET  
10/816,567 (00032.04CON)

benzotropine.

62. (new) The method according to Claim 20, wherein the drug is pergolide.
63. (new) The method according to Claim 20, wherein the drug is amantadine.
64. (new) The method according to Claim 20, wherein the drug is deprenyl.
65. (new) The method according to Claim 20, wherein the drug is ropinerole.

DRAFT CLAIM SET  
10/816,407 (00032.05CON)

1. (currently amended) A method of treating ~~Parkinsons~~ Parkinsons disease in a patient comprising administering a therapeutic amount of a ~~benztropine, pergolide, ropinoreole, amantadine or deprenyl~~ drug condensation aerosol to the patient by inhalation,

wherein the drug is selected from the group consisting of benzotropine, pergolide, ropinerole, amantadine and deprenyl, and

wherein the condensation aerosol is formed by heating a thin layer containing the drug, on a solid support, to produce a vapor of the drug, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug degradation products by weight, and having an MMAD of less than 3  $\mu$ m and less than 5% benzotropine, pergolide, ropinerole, amantadine or deprenyl degradation products, to a patient by inhalation, upon activation by the patient of the formation of, and delivery of, the condensation aerosol 5 microns.

2. (currently amended) The method of according to claim 1, wherein said condensation aerosol is formed by

a. ~~volatilizing benzotropine, pergolide, ropinerole, amantadine or deprenyl under conditions effective to produce a heated vapor of the benzotropine, pergolide, ropinerole, amantadine or deprenyl, and~~

b. ~~condensing the heated vapor of the benzotropine, pergolide, ropinerole, amantadine or deprenyl to form condensation aerosol particles wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.~~

3. (original) The method according to claim 1, wherein the condensation aerosol is formed at a rate greater than 0.5 mg/second.

4. (currently amended) The method according to claim + 26, wherein said the therapeutic amount of benzotropine condensation aerosol comprises between 0.1 mg and 4 mg of benzotropine delivered in a single inspiration.

MAY 09 2005 8:10AM ALEXZA MDC

650-687-3998

P.8

**THIS PAGE BLANK (USPTO)**

DRAFT CLAIM SET  
10/816,407 (00032.05CON)

~~amantadine or deprenyl having less than 5% benzotropine, pergolide, ropinerole, amantadine or deprenyl 10% drug degradation products by weight, and an MMAD of less than 3 microns, and~~

wherein the peak plasma drug concentration is achieved ~~reached~~ in less than 0.1 hours.

12. (currently amended) A kit for delivering a drug condensation aerosol comprising:

a) a thin coating layer containing the drug, on a solid support, wherein the drug is selected from the group consisting of benzotropine, pergolide, ropinerole, amantadine and deprenyl of an benzotropine, pergolide, ropinerole, amantadine or deprenyl composition, and

b) b. a device for dispensing said providing the thin coating as a condensation aerosol, wherein the condensation aerosol is formed by heating the thin layer to produce a vapor of the drug and condensing the vapor to form a condensation aerosol characterized by less than 10% drug degradation products by weight, and an MMAD of less than 5 microns.

13. (currently amended) The kit of claim 12, wherein the device for dispensing said coating as a condensation aerosol comprises:

(a) a flow through enclosure containing the solid support,

~~(b) — contained within the enclosure, a metal substrate with a foil-like surface and having a thin coating of benzotropine, pergolide, ropinerole, amantadine or deprenyl composition formed on the substrate surface,~~

~~(c) b. a power source that can be activated to heat the substrate to a temperature effective to volatilize the benzotropine, pergolide, ropinerole, amantadine or deprenyl composition contained in said coating solid support, and~~

~~(d) c. inlet and exit portals at least one portal through which air can be drawn through said device by inhalation,~~

~~wherein heating the substrate by activation of the power source is effective to form a benzotropine, pergolide, ropinerole, amantadine or deprenyl produce a vapor containing less than 5% benzotropine, pergolide, ropinerole, amantadine or deprenyl~~

## DRAFT CLAIM SET

10/816,407 (00032.05CON)

~~degradation products, and drawing air through said chamber is effective to condense the benzotropine, pergolide, ropinoreole, amantadine or deprenyl vapor to form aerosol particles wherein the aerosol has an MMAD of less than 3 microns of the drug, and drawing air through the enclosure is effective to condense the vapor to form the condensation aerosol.~~

14. (currently amended) The kit according to claim 13, wherein the heat for heating the substrate solid support is generated by an exothermic chemical reaction.

15. (currently amended) The kit according to claim 14, wherein said the exothermic chemical reaction is oxidation of combustible materials.

16. (currently amended) The kit according to claim 13, wherein the heat for heating the substrate solid support is generated by passage of current through an electrical resistance element.

17. (currently amended) The kit according to claim 13, wherein said substrate the solid support has a surface area dimensioned to accommodate a therapeutic dose of benzotropine, pergolide, ropinoreole, amantadine or deprenyl composition in said coating the drug.

18. (currently amended) The kit according to claim 12, wherein a peak plasma concentration of benzotropine, pergolide, ropinoreole, amantadine or deprenyl is obtained the drug is reached in less than 0.1 hours after delivery of condensation aerosol to the pulmonary system.

19. (original) The kit of claim 12, further including instructions for use.

20. (new) The method according to claim 1, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 5 microns.

DRAFT CLAIM SET  
10/816,407 (00032.05CON)

21. (new) The method according to claim 2, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 3 microns.
22. (new) The method according to claim 1, wherein the condensation aerosol comprises at least 80% drug by weight.
23. (new) The method according to claim 22, wherein the condensation aerosol comprises at least 95% drug by weight.
24. (new) The method according to claim 1, wherein the thin layer comprises at least 80% drug by weight.
25. (new) The method according to claim 24, wherein the thin layer comprises at least 95% drug by weight.
26. (new) The method according to claim 1, wherein the drug is benzotropine.
27. (new) The method according to claim 1, wherein the drug is pergolide.
28. (new) The method according to claim 1, wherein the drug is ropinerole.
29. (new) The method according to claim 1, wherein the drug is amantadine.
30. (new) The method according to claim 1, wherein the drug is deprenyl.
31. (new) The kit according to claim 12, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.
32. (new) The kit according to claim 12, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 5 microns.
33. (new) The kit according to claim 31, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 3 microns.
34. (new) The kit according to claim 12, wherein the condensation aerosol comprises at least 80% drug by weight.

DRAFT CLAIM SET  
10/816,407 (00032.05CON)

35. (new) The kit according to claim 34, wherein the condensation aerosol comprises at least 95% drug by weight.
36. (new) The kit according to claim 12, wherein the thin layer comprises at least 80% drug by weight.
37. (new) The kit according to claim 36, wherein the thin layer comprises at least 95% drug by weight.
38. (new) The kit according to claim 12, wherein the drug is benzotropine.
39. (new) The kit according to claim 12, wherein the drug is pergolide.
40. (new) The kit according to claim 12, wherein the drug is ropinerole.
41. (new) The kit according to claim 12, wherein the drug is amantadine.
42. (new) The kit according to claim 12, wherein the drug is deprenyl.
43. (new) The kit according to claim 13, wherein the solid support has a surface to mass ratio of greater than 1 cm<sup>2</sup> per gram.
44. (new) The kit according to claim 13, wherein the solid support has a surface to volume ratio of greater than 100 per meter.
45. (new) The kit according to claim 13, wherein the solid support is a metal foil.
46. (new) The kit according to claim 45, wherein the metal foil has a thickness of less than 0.25 mm.